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10/551,101	09/26/2005	Richard Mueller	ZP192-05009	1624
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MIDDLETON & REUTLINGER			EXAMINER	
2500 BROWN & WILLIAMSON TOWER			SKOLER, JAY R	
LOUISVILLE, KY 40202				
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		3733		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/551,101

Applicant(s)

MUELLER, RICHARD

Examiner

JAY R. SIGLER

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 55-68 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-15 and 55-68 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 23 April 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date 12 February 2008
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: "having a portion of female threads" is suggested to be --have a portion of female threads--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-15 and 55-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim language "wherein said at least a portion of female threads extend into said housing to a first depth and terminate above an upper surface of said rod when said rod is fully received within said housing" (see claim 1, lines 29-31, claim 55, lines 23-25, claim 62, lines 16-18, and claim 68, lines 21-23) is not considered to be supported by the original specification. The specification does not contain this language. Additionally, the drawings are not disclosed as "to scale" nor is there a drawing showing both the female threads and rod. Therefore, the drawings are not believed to support the claimed limitation.
4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15 and 55-68 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 1 recites the limitation "with said at least a portion of female threads" in lines 24-25. There is insufficient antecedent basis for this limitation in the claim. The following language is suggested: --with at least said portion of female threads-- or --with at least a portion of said portion of female threads-- with appropriate corrections to the rest of the claim.
7. Claim 55 recites the limitation "wherein said at least a portion of female threads" in line 23. There is insufficient antecedent basis for this limitation in the claim. The following language is suggested: --with at least a portion of said female threads--.
8. Claim 62 recites the limitation "said extension member" in lines 13-15. There is insufficient antecedent basis for this limitation in the claim. The following language is suggested: --said post--.
9. Claim 62 recites the limitation "wherein said at least a portion of female threads" in line 16. There is insufficient antecedent basis for this limitation in the claim. The following language is suggested: --with at least a portion of said female threads--.
10. Claim 68 recites the limitation "wherein said at least a portion of female threads" in line 21. There is insufficient antecedent basis for this limitation in the claim. The following language is suggested: --with at least a portion of said female threads--.

Response to Arguments

11. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 6-8, 10, 11, and 55-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan et al. (WO 01/52758) in view of Cotrel (U.S. Patent 5,154,719).

Yuan et al. teaches a **bone fixation apparatus for a rod system comprising: a bone anchor** (see Abstract; taken to be embodied by fastener portion) **having a proximal end** capable of **engaging a driving device and a distal end for engaging a bone; a housing** (see Abstract; taken to be embodied by head portion) **coupled to said proximal end of said bone anchor having opposed spaced-apart flanges** (230 and 232) **extending longitudinally defining a channel therebetween for receiving a rod** (228); **a locking assembly** (see Abstract: taken to be embodied by locking cap); **wherein said locking assembly further comprises an upper cap** (220a) **and a lower cap** (220b) **joined by a post** (298) **and rotatable relative one to the other** (Page 19; First Paragraph), **wherein said upper cap is a generally cylindrical member having an inner cavity** (282) **and an upper surface and**

a lower surface and wherein said inner cavity further comprises an opening to receive said post (288); and wherein said lower cap comprises an upper surface and a lower semi-cylindrical surface (299) for engaging said rod.

The rod is insertable in the channel and the locking assembly is used to lock the rod into the housing (see Abstract). The post has an outer perimeter with a first profile and the opening has a second profile that is geometrically similar (see Fig. 12A-B). The two profiles can be considered to allow one orientation, i.e. where the center axis of the post and center axis of the hole align. The lower cap has a first orientation means 302. Yuan et al. does not teach the threaded engagement between the locking assembly and the housing, but does teach a means (284, 286, 294, and 296) for a locking engagement between the locking assembly and the housing.

Cotrel teaches a bone fixation apparatus including a locking system (10, 11, and 12) that uses a threaded engagement (7 and 9) in order to lock the rod in translation and in rotation (see Abstract). It would have been obvious to substitute the locking engagement of Yuan et al, in view of Cotrel, with a threaded engagement because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The predictable results being creating a locking engagement between the locking assembly and housing. Further, Yuan et al teaches the locking engagement to terminate at an above an upper surface of the rod (see Fig. 13), which in the modified invention would have been the

threads, or alternatively a portion of the threads of Cotrel can be considered above the rod height (the other portion being below the rod height). Additionally, the depth of the threads is considered a result effective variable because the depth of the threads would determine how far the upper cap can enter the housing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the female threads terminate above the rod height in the invention of Yuan et al., in view of Cotrel, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). *Note*: applicant places no criticality on the depth of the threads

Concerning claims 2, 3, 6, 7 and 10, Yuan et al. includes different embodiments of the bone anchor including a fixed screw (Figure 1; 26), fixed hook (Figure 1; 46), or polyaxial screw (Figure 13, 226).

Concerning claims 4, 8, and 11, Yuan et al. teaches an extension 302 of the lower cylindrical surface.

Concerning claims 56-61 and 63-67, Yuan et al., in view of Cotrel, can be considered to suggest the claimed limitations, depending on where the axes and planes are considered to be.

3. Claims 5, 9, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan et al. (WO 01/52758) in view of Cotrel (U.S. Patent 5,154,719) as applied to claims 4, 8, or 11 above, and further in view of Richelsoph et al. (U.S. Patent Application 2003/0187442). Yuan et al., in view of Cotrel, fairly suggests the invention

as show above, but does not fairly suggest timing the threads. Richelsoph et al. teaches carefully controlling and timing threads in order to guarantee an element stops exactly where it must (Paragraph [0015]). It would have been obvious to someone of ordinary skill in the art at the time of the invention to time the threads in the invention of Yuan et al., in view of Cotrel, in order to guarantee an element stops exactly where it must. Concerning claims 13 and 14, Yuan et al. teaches a the screw having a depression (Figure 12a; seen at the top of the screw 214) and the housing has an appurtenance (234; embodied by something subordinate to another, more important thing; appurtenance. (n.d.). *Dictionary.com Unabridged* (v 1.1). Retrieved October 17, 2007, from Dictionary.com website:

<http://dictionary.reference.com/browse/appurtenance>

4. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan et al. (WO 01/52758) in view of Cotrel (U.S. Patent 5,154,719) and Richelsoph et al. (U.S. Patent Application 2003/0187442) as applied to claim 14 above, and further in view of Bono et al. (U.S. Patent 6, 755, 829). Yuan et al., in view of Cotrel, fairly suggests the invention as shown above and a means (232 and 234) for keeping the polyaxial screw in the housing, but does not fairly suggest using a depression and appurtenance to keep the screw in the housing. Bono et al. teaches using a depression (between 146) and appurtenance (158) to keep two elements (140 and 153) together (see Abstract; Lines 10-13; taken to be embodied by a bayonet mount). It would have been obvious to substitute the means of Yuan et al, in view of Cotrel and Richelsoph, with the means of Bono et al. because the substitution of one known element for another would have

yielded predictable results to one of ordinary skill in the art at the time of the invention. The predictable results being keeping elements together, namely the housing and bone screw.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAY R. SIGLER whose telephone number is (571)270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733